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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/616,047	07/07/2003	Robert Lee Smith	0723	9786
21837	7590	03/01/2005	EXAMINER	
LORI M FRIEDMAN 300 BENTON VIEW DRIVE PHILOMATH, OR 97370			PAK, JOHN D	
			ART UNIT	PAPER NUMBER
			1616	

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/616,047	Applicant(s) SMITH ET AL.	
	Examiner JOHN PAK	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 9-23 and 25-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/7/03</u> . | 6) <input type="checkbox"/> Other: _____ |

Claims 1-27 are pending in this application.

Applicant's election of the invention of Group I in the reply filed on 12/3/2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Accordingly, claims 9-23 and 25-27 are withdrawn from further consideration as being directed to non-elected subject matter. Claims 1-8 and 24 will presently be examined.

Applicant is advised to amend "that dispensed by a consumer" to "that is dispensed." The verb "is" is needed, and reference to a "consumer" should be avoided for a system or composition feature in the present context.

Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 depends on claim 1, which is directed to a packaged aqueous solution of hydrogen peroxide. Claim 7 recites an application step, which is a process claim feature. Therefore, the packaged aqueous solution of hydrogen peroxide per se cannot be further modified by how it is to be used or applied.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by
Saferstein et al. (US 6,086,856).

Saferstein et al. disclose a propellantless foam dispensing system for dispensing as a foam oral antimicrobials (column 5, lines 15-20; column 6, lines 12-13, 21-22 and 39-40). Oral antimicrobials include 0.1-3 wt% hydrogen peroxide (column 6, lines 39-40). Water as a carrier solvent is disclosed (column 6, lines 5-7). Surfactants are present at 0.1-1.5 wt%, and polysorbate 80 is disclosed as a suitable surfactant (column 7, lines 18-41). Reversibly compressible and decompressible container separately housing the foamable solution and foam-producing amount of air is disclosed (claims 1, 6; column 5, lines 21-58). The container operates at atmospheric pressure (column 5, lines 31-50). Simple compressing of the container increases the pressure of the air within the container, thereby providing sufficient driving force to produce and dispense foam from the container (column 5, lines 40-44).

The claims are thereby anticipated. Applicant's "stabilizer" component is noted in claims 1 and 3, but "less than 1%" is open to 0%, so Saferstein's system still anticipates the claims. The feature, "delivers H₂O₂ topically to a wound by finger-depression of a

foam dispenser" is clearly met by Saferstein's compressible and decompressible container and foam pumping system. Additionally, actual topical delivery to a wound or finger-depression is not necessary for anticipation of the claimed foam system per se so long as Saferstein's foam system is necessarily capable of being finger-depressed to topically deliver the foam to a wound. Here, the compressible and decompressible container using foam system taught by Saferstein et al. would deliver the antimicrobially active hydrogen peroxide as a foam when depressed using finger(s), so such claimed feature is inherently met by Saferstein's disclosure. Addition of a topical pain reliever or skin protectant such as menthol, glycerol or propylene glycol is explicitly disclosed by Saferstein et al. (column 6, line 9; column 7, lines 56-61). As for 1% surfactant, it is the Examiner's position that Saferstein's 0.1 to 1.5 wt% surfactant range clearly and explicitly discloses 1%. One of ordinary skill in the art would readily envisage 1% from such a range. Lastly, the feature of claim 7 does not alter the foam dispensing system per se of claim 1 (as discussed earlier in this Office action), because it is an improper method feature; hence, this feature does not change the finding of anticipation.

For these reasons, claims 1-8 are anticipated.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-8 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saferstein et al.

Applicant is advised that in this alternative ground of rejection, the Examiner considers the presence of a stabilizer such as sodium pyrophosphate at an amount greater than 0% and presents alternative rationale for obviousness of incorporating additional ingredients such as topical pain reliever and/or skin protectant.

Teachings of Saferstein et al. have been fully discussed in the preceding ground of rejection, and the discussion there is incorporated herein by reference to avoid repetition. Additionally, it is noted that Saferstein et al. disclose the use of the alkalizer and anti-plaque adjuvant tetrasodium pyrophosphate at 0.1 to 1 wt% (column 8, lines 43-44; see also column 7, lines 65-66). Note, tetrasodium pyrophosphate is the same substance as "sodium pyrophosphate." Because 0.1% up to 1% is disclosed, "less than 1% is amply suggested, e.g. 0.1%.

Even though Saferstein et al. do not expressly state in verbatim language that their hydrogen peroxide foam system is to be applied to a wound site, Saferstein et al. teach that their antimicrobial oral foam is to be used for oral therapy (column 11, line 43), treatment of tooth decay, gingivitis and periodontal disease (column 3, lines 5-7), which incorporates components such as healing agents and analgesics (column 6, lines

8-9). Such disclosure fairly suggests at least administration of the foam to an oral wound, wherein the term "topical wounds," given its broadest reasonable interpretation during examination, includes such oral wound.

The ordinary skilled artisan would have been motivated to add sodium pyrophosphate for its anti-plaque and alkalizing effect, menthol for its flavoring effect, an analgesic to relieve oral or periodontal pain, and glycerol or propylene glycol for their humectant and demulcent effects (column 8, lines 41-44; column 7, lines 56-66). The motivation arises from the advantage of not only obtaining antimicrobial effect with hydrogen peroxide, but also from the advantage of obtaining additional therapeutic and adjuvant benefits for patient comfort.

The claimed features of propellantless, finger activated, foam pumping system, in a reversibly compressible and decompressible container that operates at atmospheric pressure, have been already found to be met by the previous discussion of Saferstein et al., which discussion have been incorporated herein by reference.

Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

Art Unit: 1616

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to JOHN PAK whose telephone number is **(571)272-0620**.


The Examiner can normally be reached on Monday to Friday from 8 AM to 4:30 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's SPE, Gary Kunz, can be reached on **(571)272-0887**.

The fax phone number for the organization where this application or proceeding is assigned is **(571)273-8300**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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